

## REMARKS

### Status of the claims

Claims 1-54 are pending and claims 1-18 and 35-54 are presently under consideration in this application, claims 19-34 having been withdrawn from consideration on the ground that they are drawn to separate inventions. All the claims presently under consideration stand rejected. After entry of the amendments made herein, claims 1-18 and 35-54 will be pending and claims 1-18 and 35-54 will be under consideration in this application, claims 19-34 having been cancelled without prejudice to their being pursued in a separate application.

### Incorrect amendment of claim 17

Applicant apologizes for inadvertently not underlining added text in amending claim 17 in the Amendment and Response filed December 23, 2003. The amendment is repeated herein, including the underlining of the relevant added text.

### 35 U.S.C. § 112, first paragraph, rejections

(a) Claims 1-18 stand rejected on the grounds that the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. Applicant respectfully traverses the rejection.

From the comments on page 4, lines 3-14, of the Office Action, Applicant understands the Examiner's position to be that the listed claims are not enabled because the references (Brusasca et al., Scand. J. Immunol. 54:448-452, 2001; Daugelet et al., Microbes and Infection, 5:1082-1095, 2003) referred to in the Amendment and Response filed December 23, 2003, did not: (a) demonstrate the elicitation by *Mycobacterium tuberculosis* of antibodies specific for all eight proteins recited in the claims; and (b) show that the antibodies elicited by *M. tuberculosis* did not react with other of other Mycobacteria. Applicant does not agree with this position for the following reasons.

With respect to issue (a), Applicant points out that the only protein not tested by the authors of either of the two references is the MTBN6 protein and reminds the Examiner that the

authors of the Daugelet et al. were unable, because of technical problems in producing recombinant MTBN6 protein, to test for presence of antibodies specific for it in sera from tuberculosis patients and *M. tuberculosis*-infected mice (see Amendment and Response filed December 23, 2003, page 13, lines 13-15). In view of the demonstration by the authors of the Daugelet et al. of the presence in relevant sera of antibodies specific for all the other seven proteins and the demonstration by the authors of the Brusasca et al. reference of the presence in relevant sera of antibodies specific for the MTBN1, MTBN2, MTBN3, MTBN4, and MTBN7 proteins, one of skill in the art reading the two references would believe it extremely likely that the relevant sera would also contain antibodies specific for the MTBN6 protein. Notwithstanding this consideration, in order to expedite prosecution of the instant application, Applicant has deleted the MTBN6 protein from the claims without prejudice to her pursuing similar claims specifying the MTBN6 protein in one or more separate applications.

With respect to issue (b), Applicant draws the Examiner's attention to the definitions on page 7, line 23, to page 8, line 7, of the instant specification that state in relevant part:

polypeptides that have "*Mycobacterium tuberculosis* specific antigenic properties" are polypeptides that: (a) can be recognized by and bind to antibodies elicited in response to *Mycobacterium tuberculosis* organisms or wild-type *Mycobacterium tuberculosis* molecules (e.g., polypeptides); . . . [and] polypeptides that have "*Mycobacterium tuberculosis* specific immunogenic properties" are polypeptides that: (a) can elicit the production of antibodies that recognize and bind to *Mycobacterium tuberculosis* organisms or wild-type *Mycobacterium tuberculosis* molecules (e.g., polypeptides).

From these definitions it is clear that the term "*Mycobacterium tuberculosis* specific antigenic and immunogenic properties" in the claims does not require that MTBN protein-binding antibodies elicited by exposure of a subject to *M. tuberculosis* bacteria not bind to proteins (or any molecules) of other *Mycobacteria*. Polypeptides that have *M. tuberculosis* specific antigenic properties need only be able to bind to antibodies elicited by *M. tuberculosis* bacteria (or wild-type *M. tuberculosis* molecules) and polypeptides that have *M.*

*tuberculosis* specific immunogenic properties need only be able to elicit the production of antibodies that bind to *M. tuberculosis* bacteria (or wild-type *M. tuberculosis* molecules).

In view of the above considerations, Applicant respectfully requests that the rejection be withdrawn.

(b) Claims 17 and 53 stand rejected on the grounds that the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims.

Applicant assumes that the Examiner intended to recite "claim 53", rather than "claim 37", in the last sentence on page 4 of the Office Action.

From the comments on page 4, lines 19-21, of the Office Action, Applicant understands the Examiner's position to be that Applicant's argument to this rejection in the Amendment and Response filed on December 23, 2003, was not found persuasive because the amendment made to claim 17 in that Amendment and Response has not been entered because it was improperly made. Applicant submits thus that, in view of the proper amendment to claim 17 made herein, the rejection is moot.

35 U.S.C. § 112, second paragraph, rejections

Claims 18, 36-52, and 54 stand rejected as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

From the comments on page 5, lines 14-16, of the Office Action, Applicant understands the Examiner's position to be that Applicant's inadvertent omission of the word "been" after "exposed" in the term "said subject exposed to *Mycobacterium tuberculosis*" renders claim 18 indefinite. Applicant apologizes for this typographic error and submits that the addition of the word "been" as indicated above renders the rejection moot.

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From the comment on page 5, line 20, Applicant understands the Examiner's position to be that, because claims 36-52 depend from rejected claims, they are indefinite. Applicant respectfully submits that, in view of the fact that (for the reasons given above) these claims are allowable, the rejection is moot.

CONCLUSIONS

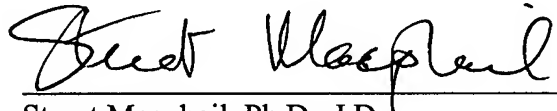
Applicant submits that the pending claims patentably define the invention and request that the Examiner permit the pending claims to pass to allowance.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's undersigned representative can be reached at the telephone number listed below.

Enclosed is a Notice of Appeal, a request for an automatic extension of time, and checks in payment of the Notice of Appeal and the extension in time. Please apply any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 07763-043001.

Respectfully submitted,

Date: 8/19/04

  
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